

**510(k) SUMMARY****MAY 13 2008**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SDMA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K080337

**1. Submitter's Identification:**

Microlife Intellectual Property GmbH, Switzerland

Espenstrasse 139  
9443 Widnau / Switzerland

Date Summary Prepared: Jan. 11, 2008

**2. Name of the Device:**

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MQ1-2D

**3. Information for the 510(k) Cleared Device (Predicate Device):**

- a. Microlife Upper Arm Automatic Blood Pressure Monitor, Model BP3BT0-1, K#013485, Microlife Corporation.
- b. AfibAlbert™, K#052767, Lechnologies Research, Inc.

**4. Device Description:**

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MQ1-2D is designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive MAM (Microlife Average Mode) technique in which an inflatable cuff is wrapped around the upper arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic capacitive pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well - known technique in the market called the "oscillometric method".

The device detects the appearance of atrial fibrillation during measurement and the atrial fibrillation symbol "AF" is displayed on the LCD screen if any atrial fibrillation signal has been detected.

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**5. Intended Use:**

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MQ1-2D is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm.

The device detects the appearance of atrial fibrillation during measurement and gives a warning signal with the reading once the atrial fibrillation is detected.

**6. Comparison to the 510(k) Cleared Device (Predicate Device):**

The modified device model BP3MQ1-2D and the predicate device model BP3BT0-1 use the well-known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. An upper arm cuff is inflated automatically, deflate rate is controlled by a factory set bleed valve and the deflation pressures are transferred via tubing to a sensor.

The solely differences between the two models are the additional features such as atrial fibrillation detection function. However, the difference does not affect the accuracy and normal use of this device.

Atrial fibrillation detection function of BP3MQ1-2D is similar with what is used in predicate device AfibAlert™, with 510(k) cleared number K#052767. The input data from the blood pressure signals (data) from BP3MQ1-2D will produce a substantially equivalent outcome as the predicate AfibAlert™ getting the input data from an ECG signal (data). They are processed by an algorithm and both output atrial fibrillation diagnostic information.

**7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Testing information demonstrating safety and effectiveness of the Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MQ1-2D in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance requirements.

The following testing was conducted:

- a. Reliability Test - Storage test
- b. Reliability Test - Operating test
- c. Reliability Test - Vibration test
- d. Reliability Test - Drop test
- e. Reliability Test - Life test
- f. EMC Test
- g. IEC 60601-1 Safety Test

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was

our conclusion that Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MQ1-2D tested met all relevant requirements of the aforementioned tests.

## 8. Discussion of Clinical Tests Performed:

For clinical validation the atrial fibrillation function, AfibAlert™ algorithm was tested using published available annotated MIT-BIH AFIB database, which showed a 92% sensitivity value and a 96% specificity value.

The BP3MQ1-2D was tested in two clinical trials which compared the atrial fibrillation (AF) readings from the BP3MQ1-2D to the rhythm determined by an electrocardiogram (ECG). The studies, Trial of Regular versus Irregular Pulse to Prevent Stroke (TRIPPS) 1.0 and 1.1, enrolled 205 and 157 subjects, respectively. All subjects in TRIPPS 1.0 and all, but one subject, in TRIPPS 1.1 had three atrial fibrillation readings performed with the BP3MQ1-2D. The results comparing the BP3MQ1-2D readings to the ECG readings read in a blinded fashion are shown in the table 1. The BP3MQ1-2D detected atrial fibrillation with a sensitivity ranging from 93% to 98% and a specificity ranging from 82-88%.

	ECG reading		Sensitivity	Specificity
BP3MQ1-2D reading	AF	Non-AF		
<b>TRIPPS 1.0</b>			98.1%	88.2%
AF	156	54	(96-99%)	(85-91%)
Non-AF	3	402		
<b>TRIPPS 1.1</b>			92.9%	81.7%
AF	92	68	(88-98%)	(78-86%)
Non-AF	7	303		
<b>Combined</b>			96.1%	85.2%
AF	248	122	(94-98%)	(83-88%)
Non-AF	10	705		

Table 1. Results for individual readings by the device compared to ECG. The last two columns show the sensitivity and specificity and the 95% confidence intervals in parentheses.

In a second analysis of these results, the three sequential readings done in each subject were used to determine a single final reading based on which reading was most frequent. Thus if two or all three of the readings for a given patient showed atrial fibrillation then the combined final reading was atrial fibrillation. If none or only one of the three readings showed atrial fibrillation then the combined final reading

was not atrial fibrillation. The results of this analysis is shown in the table 2. Using the combined three sequential readings, the BP3MQ1-2D detected atrial fibrillation with a sensitivity ranging from 94% to 100% and a specificity ranging from 85-90%.

	ECG reading		Sensitivity	Specificity
BP3MQ1-2D reading	AF	Non-AF		
<b>TRIPPS 1.0</b>			100.0%	89.5%
AF	53	16	(92-100%)	(83-94%)
Non-AF	0	136		
<b>TRIPPS 1.1</b>			93.9%	85.4%
AF	31	18	(78-99%)	(78-91%)
Non-AF	2	106		
<b>Combined</b>			97.7%	87.7%
AF	84	34	(91-100%)	(83-91%)
Non-AF	2	242		

Table 2. Results for the three sequential readings combined compared to the ECG. The last two columns show the sensitivity and specificity and the 95% confidence intervals in parentheses.

Based upon the aforementioned information, the requirement to develop an atrial fibrillation detection module for the BP3MQ1-2D to detect atrial fibrillation that is added to the existing firmware included in the BP3BT0-1 has been met.

#### 9. **Software information:**

Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA November 2005 document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

#### 10. **Conclusions:**

It has been demonstrated that there is no difference between the Microlife Upper Arm Automatic Digital Blood Pressure Monitor Model BP3MQ1-2D and the predicate model BP3BT0-1 in terms of safety and effectiveness based on electrical, mechanical and environmental test results, the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", and the ANSI/AAMI Voluntary Standard, SP10: 2002 test results.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 13 2008

Microlife Intellectual Property GmbH  
c/o Ms. Susan Goldstein-Falk  
Official Correspondent  
mdi Consultants, Inc.  
55 Northern Blvd., Suite 200  
Great Neck, NY 11021

Re: K080337  
Microlife Upper Arm Automatic Digital Blood Pressure  
Monitor, Model BP3MQ1-2D  
Regulation Number: 21 CFR 870.1130  
Regulation Name: Noninvasive blood pressure measurement system  
Regulatory Class: Class II (two)  
Product Code: DXN  
Dated: April 17, 08  
Received: April 18, 2008

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

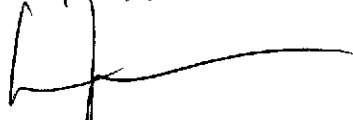
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', with a long horizontal flourish extending to the right.

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

EXHIBIT B

Indications for Use

510(k) Number (if known): K080337

Device Name: Microlife Upper Arm Automatic Digital Blood Pressure Monitor,  
Model BP3MQ1-2D

Indications For Use:

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The device detects the appearance of atrial fibrillation during measurement and gives a warning signal with the reading once the atrial fibrillation is detected.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K080337